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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,344	04/27/2000	Claude Negrier	06478.1442	2949

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EXAMINER	
SCHNIZER, HOLLY G	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/559,344	NEGRIER ET AL.	
	Examiner	Art Unit	
	Holly Schnizer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9-12,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9-12,15 and 16* is/are rejected.

7)☒ Claim(s) *2-4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 April 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

The Amendment filed November 4, 2003 has been entered and considered. Claims 1-4, 9-12, and 15-16 are pending and have been considered in this Office Action.

Drawings

The drawings have been approved by the draftsperson.

Rejections Withdrawn

Claim Rejections Withdrawn- 35 USC § 103

The rejection of Claims 1-3 and 5-13 under 35 U.S.C. 103(a) as being unpatentable over Hao et al. (Human Gene Therapy (July 1995) 6: 873-880) in view of Uzan et al. (J. Biol. Chem. (1991) 266(14): 8932-8939) and Romp et al. (Blood Coagulation and Fibrinolysis (1993) 4: 905-910) is withdrawn in light of Applicants amendment and arguments.

The rejection of Claim 4 under 35 U.S.C. 103(a) as being unpatentable over Hao et al. Uzan et al., and Romp as applied to claims 1-3 and 5-14 above, and further in view of Kurachi et al. (J. Biol. Chem. (1995) 270(10): 5276-5281; cited in IDS of Paper No. 2) is withdrawn in light of the Amendments and Applicants arguments.

Claim Rejections Withdrawn- 35 USC § 112

The rejection of Claim 5 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for the production of Factor IX in a hematopoietic cell line in vitro, does not reasonably provide enablement for a process for the production of Factor IX in hematopoietic cells in vivo (gene therapy) is withdrawn in light of the cancellation of Claim 5.

New Rejections

Upon an update of a prior art search, a new reference was found that was considered to meet all of the limitations of several of the pending claims. A discussion of the prior art reference is discussed in the reference below.

In addition, the amendment to Claim 9 raises new issues of enablement. The rejection is discussed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Ginsberg et al. (U.S. Patent No. 6,066,778).

Ginsberg et al. teach methods of making a transgenic animal expressing factor V proteins (see abstract) wherein DNA constructs identical to that of present Claim 1 are used. The constructs described by Ginsberg et al. comprise factor V (FV) (a blood coagulation factor) cDNA under the control the rat platelet factor 4 (PF4) promoter (a megakaryocyte specific promoter) for tissue specific expression in megakaryocytes (see Col. 19, lines 9-17 and lines 31-50). Thus, Ginsberg et al. meets the limitations of Claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-12 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for the production of a blood coagulation factor in a megakaryocyte cell line by transfecting a megakaryocyte cell line with a DNA construct comprising DNA encoding a blood coagulation factor and

a megakaryocyte specific promoter, does not reasonably provide enablement for a process for the production of a blood coagulation factor in any hematopoietic cell by transfecting any hematopoietic cell with a DNA-construct comprising a blood coagulation factor and a megakaryocyte specific promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims encompass methods of producing blood coagulation factors in any hematopoietic cell line by transfecting any hematopoietic cell with a DNA construct encoding the blood coagulation factor and a promoter specific for expression in megakaryocytes. The phrase "specific for expression in megakaryocytes" is interpreted to mean that the promoter only functions (expression occurs) in megakaryocytes and would not function (would not result in expression) in other hematopoietic cells. Thus, one of skill in the art could not produce a blood coagulation factor in hematopoietic cells other than megakaryocytes using a DNA construct wherein the DNA encoding the blood coagulation factor is under control of a promoter that is specific for expression in megakaryocytes.

This rejection could be overcome by substituting "hematopoietic" in lines 2 and 3 of Claim 9 with "megakaryocyte".

Claim Objections

Claims 2-4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusions

Claims 1, 9-12, and 15-16 are rejected for the reasons stated above. Claims 2-4 are objected to but would be allowable if rewritten in independent form and included all of the limitations of Claim 1.

The examiner notes that Claim 9 is not considered to be anticipated over Ginsberg et al. since the claimed process is drawn to producing blood coagulation factors in vitro (in hematopoietic cell lines). The DNA construct of Ginsberg et al. is used to transfect embryonic stem cells obtained by culturing pre-implantation embryos. Thus, the cells transfected in Ginsberg et al. are from a primary cell culture and not a cell line. In addition, Ginsberg et al. does not suggest expressing the DNA-construct disclosed therein in a megakaryocyte cell line.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Tuesday, Thursday, and Friday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Holly Schnizer
February 12, 2004

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